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### REMARKS

Applicants thank the Examiner for the courtesy of a telephone interview on August 25, 2003.

By this amendment, Applicants have amended Claims 1, 7, 8, and 10, and added new Claims 46-58. Claims 11-20, 22-28, and 42-45 are cancelled without prejudice for prosecution in a divisional application. Claims 1-4, 7, 8, 10, and 46-58 are now pending in the above-identified application. No new matter is introduced in amended Claims 1, 7, 8 and 10, or in new Claims 46-58, which are presented to address the Advisory Action and to advance prosecution of the case. Reexamination and reconsideration of the application are requested in view of these amendments and the following remarks.

#### *Claim Rejections under 35 U.S.C. §112, first paragraph*

The Examiner maintains rejection of Claims 1-6 and 10 under 35 U.S.C. §112, first paragraph, for reasons of inadequate written description as previously set forth in the Office Action mailed December 17, 2002.

Claim 6 was previously cancelled in the Response filed March 14, 2003, thereby rendering the rejection of Claim 6 moot. Applicants request withdrawal of the rejection of Claim 6.

Applicants respectfully reassert that Claim 1 indicates the distinguishing attributes shared by the members of the claimed genus. The members of the genus claimed in Claim 1 are 2 to 20 base, 3'-OH, 5'-OH synthetic phosphodiester oligonucleotides. The members of the claimed genus also share the distinguishing feature of comprising GT-containing nucleotide sequences defined by  $(G_xT_y)_n$ , wherein x and y is an integer between 1

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and 7, and n is an integer between 1 and 12. Another distinguishing feature is the ability to induce a response in an animal having cancer. These distinguishing features are described in the Specification on page 9, lines 17-24. Further, in Examples 4-37, the Specification provides a number of species of the claimed genus and describes the characteristics identifying the members of the genus. For example, the Specification states, on page 16, lines 5-6, that "Jurkat T cell proliferation was inhibited by the GT sequences tested, but not by the CT sequence tested", on page 26, lines 2-4, that "6 base GT-phosphodiester sequences inhibited Jurkat T, LNCaP and MCF-7 cell proliferation more effectively than 6 base GT-phosphorothioate sequences", and, on page 27, lines 4-7, that "substitution of a sulfur atom for a nonbridging oxygen atom on one or more phosphate groups of 6 base GT SEQ ID NO:25 resulted in a significant decrease in inhibition of Jurkat T and MCF-7 cell proliferation."

In addition to these statements asserted by Applicants in the response filed March 14, 2003 and included in this response, Applicants also respectfully assert that the specification provides numerous representative species to support the genus recited in Claim 1. The sequences disclosed in the specification include over eighty 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 2, 3, 4, 5, 6, 7, 9, 11, 12, 14, 15, 18, 24, 33 and 45 bases in length.

Applicants respectfully assert that the disclosure provides sufficient description of the defining features of the claimed genus, and a representative number of species. In view of the foregoing, Applicants respectfully request withdrawal of the rejection of Claims 1-6 and 10 under 35 U.S.C. §112, first paragraph.

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*Claim Rejections under 35 U.S.C. §102*

The Examiner maintains rejection of Claims 1-3, 5, 7, and 8 under 35 U.S.C. §102(b) as anticipated by *Frank et al.* (International Patent Application PCT/EP96/02427) for reasons set forth in the Office Action of December 17, 2002.

Applicants respectfully reassert their position that *Frank et al.* does not anticipate Applicants' compositions recited in Claim 1 as previously presented. *Frank et al.* does not teach a composition comprising the 3'-OH, 5'-OH synthetic phosphodiester oligonucleotide sequence SEQ ID NO:45. SEQ ID NO:45 is a synthetic phosphodiester hexaoligonucleotide GGGAGG possessing a hydroxyl group both at the 5' position of the sugar (5'-OH) of the first guanidine and at the 3' position of the sugar (3'-OH) of the last guanidine. None of the oligonucleotides taught in *Frank et al.* is the 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG with hydroxyl groups both at the 5' and at the 3' positions. Oligonucleotide Accession No. AAT80306 is a nine-base oligonucleotide HCV-186 CCCGGGAGG taught in *Frank et al.*, not a 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG (SEQ ID NO:45). Unlike the 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG (SEQ ID NO:45) claimed by the Applicants, the sequence GGGAGG contained within the larger sequence CCCGGGAGG of the oligonucleotide Accession No. AAT80306 does not possess hydroxyl groups both at the both at the 5' and at the 3' positions. The 5' carbon of the sugar of the third guanidine in the sequence CCCGGGAGG is joined via a phosphodiester bond with the 3' carbon of the previous cytidine. For at least this reason, compositions claimed by the Applicants' in Claim 1 as previously presented are different chemical entities that those disclosed in *Frank et al.*

Applicants also respectfully assert that *Frank et al.* does not anticipate Applicants' compositions as claimed in amended Claim 1 and dependent Claims 2-3, 5, 7,

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and 8. Applicants' claimed compositions are 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 2-20 bases in total. Applicants' have reviewed *Frank et al.* and do not find disclosure of 3'-OH, 5'-OH synthetic phosphodiester nucleotides. Accordingly, *Frank et al.* does not teach an element of Applicants' compositions, as claimed, namely that they are 3'-OH, 5'-OH synthetic phosphodiester nucleotides. Applicants' claimed compositions are different chemical compositions of matter than those disclosed in *Frank et al.* Accordingly, since Applicants' claimed compositions are different chemical entities than those disclosed in *Frank et al.*, Applicants respectfully assert that *Frank et al.* does not anticipate Applicants' claimed compositions. In view of the foregoing, Applicants respectfully assert that Claims 1-3, 5, 7, and 8 are not anticipated by *Frank et al.* Applicants respectfully request withdrawal of the rejection.

Applicants further assert that *Frank et al.* does not teach a composition consisting of the 3'-OH, 5'-OH synthetic phosphodiester oligonucleotide sequence SEQ ID NO:45, a pharmaceutically acceptable carrier, and, optionally, a chemotherapeutic agent. Applicants respectfully bring to the Examiner's attention that the oligonucleotide (or "sequence", as defined by the Specification on page 5, line 23) SEQ ID NO:45 is a 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG. *Frank et al.* does not teach a 3'-OH, 5'-OH hexaoligonucleotide GGGAGG (see *Sequence Listing* in *Frank et al.*, pages 58-82). None of the oligonucleotides taught on page 17 of *Frank et al.* is the 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG. Oligonucleotide Accession No. AAT80306 is a nine-base oligonucleotide HCV-186 CCCGGGAGG taught in *Frank et al.*, not a 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG (SEQ ID NO:45).

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In view of at least all the foregoing comments and reasons, Applicants respectfully assert that Claims 1-3, 5, 7, and 8 are not anticipated by *Frank et al.* Applicants request withdrawal of the rejection under 35 U.S.C. §102(b).

Applicants' note that Claim 4 was not rejected in view of *Frank et al.* New Claim 46 is based on Claim 4 and recites 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 2 to 7 bases in length. New Claim 47 recites 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 6 bases in length. Applicants request favorable consideration of these claims and the claims that depend from them.

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CONCLUSION

The foregoing is submitted as a full and complete response to the Advisory Action mailed August 29, 2003.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 or to John McDonald, Ph.D. at (404) 745-2470 is respectfully solicited.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,

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